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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,712	11/08/2005	Marc Eloit	270423US0XPCT	9314

22850 7590 11/26/2008

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EXAMINER	
BURKHART, MICHAEL D	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
11/26/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/530,712	ELOIT ET AL.	
	Examiner	Art Unit	
	Michael Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *22-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the cancellation of all previously pending claims and submission of new claims 22-60 in the reply of 8/29/2007, restriction is required as set forth below.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 22-24, 26-36, 52-55, drawn to recombinant, replicating, and infectious adenoviruses comprising (as best understood from the claim language) a deletion of the region corresponding to positions 311-319 of SEQ ID NO: 12, and methods of using the adenovirus. Note, claim 55 recites a plasmid of claim 57, however, claim 57 is drawn to a method. For the sake of compact prosecution, claim 55 has been interpreted as being dependent from claim 52.

Group II claim(s) 37, drawn to a method of making a recombinant protein using the adenovirus of Group I.

Group III, claim(s) 25, drawn to a recombinant, replicating, and infectious adenovirus comprising (as best understood from the claim language) a deletion of the region corresponding to positions 318-401 of SEQ ID NO: 12.

Group IV, claim(s) 38-50, drawn to recombinant, replicating, and non-infectious adenoviruses comprising (as best understood from the claim language) a deletion of the region corresponding to positions 311-499 of SEQ ID NO: 12, and methods of using the adenovirus to treat a subject.

Group V claim(s) 51, drawn to a method of making a recombinant protein using the adenovirus of Group IV.

Group VI, claim(s) 56-60, drawn to a method of preparing a recombinant adenovirus in a prokaryotic cell via homologous recombination by introducing into the cell: 1) a plasmid comprising the adenoviral genome and a selection gene; and, 2) a linearized DNA comprising a heterologous sequence flanked by sequences that are homologous to those within the plasmid.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. All the groups are directed towards adenovirus vectors and methods, but each group has a different special technical feature not shared by the remaining groups, as set forth below.

The special technical feature of Group I is considered to be a recombinant, replicating, and infectious adenoviruses comprising a deletion of the region corresponding to positions 311-319 of SEQ ID NO: 12. This special technical feature is not found in Groups III-VI.

Note: Group I also requires that the A_I to A_{XII} encapsidation signals be present.

The special technical feature of Group II is considered to be a method of making a recombinant protein using the adenovirus of Group I. This special technical feature is not found in Groups III-VI.

The special technical feature of Group III is considered to be a recombinant, replicating, and infectious adenovirus comprising a deletion of the region corresponding to positions 318-401 of SEQ ID NO: 12. This special technical feature is not found in the other Groups.

Note, given the language of claim 25 that the deleted portion "comprises all or a part of... positions 318-401 of SEQ ID NO: 12", this would require deletion of the A_X to A_{XII} encapsidation signals. This is apparently outside the scope of Group I.

The special technical feature of Group IV is considered to be recombinant, replicating, and non-infectious adenoviruses comprising a deletion of the region corresponding to positions 311-499 of SEQ ID NO: 12. This special technical feature is not found in Groups I-III (which recite an infectious adenovirus), or Group VI.

The special technical feature of Group IV is considered to be a method of making a recombinant protein using the adenovirus of Group III. This special technical feature is not found in Groups I-III (which recite an infectious adenovirus), or Group VI.

The special technical feature of Group VI is considered to be a method of preparing a recombinant adenovirus in a prokaryotic cell via homologous recombination by introducing into the cell: 1) a plasmid comprising the adenoviral genome and a selection gene; and, 2) a linearized DNA comprising a heterologous sequence flanked by sequences that are homologous to those within the plasmid. This special technical feature is not found in the other Groups.

Group II is the second method of use claimed for the adenoviruses of Group I, the first such use being the methods of treating a subject as recited in claims 32-36-50. The two methods

differ in the outcome and method steps, the first requires administration of the adenovirus to a subject (e.g. a human, claim 50) while the second method requires no such administration step, merely introduction of the adenovirus into a host cell, which could be *in vitro*, a prokaryotic cell, etc. Therefore, although the Groups share a technical feature, Group IV is a distinct invention according to 37 CFR §1.475.

Group V is the second method of use claimed for the adenoviruses of Group IV, the first such use being the methods of treating a subject as recited in claims 46-50. The two methods differ in the outcome and method steps, the first requires administration of the adenovirus to a subject (e.g. a human, claim 50) while the second method requires no such administration step, merely introduction of the adenovirus into a host cell, which could be *in vitro*, a prokaryotic cell, etc. Therefore, although the Groups share a technical feature, Group IV is a distinct invention according to 37 CFR §1.475.

Accordingly, Groups I-VI are not so linked by the same concept or a corresponding technical feature as to form a single general inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species Election I, elect one of the types of unmodified adenoviruses as recited in claims 29 or 30, for example;

Species Election II, elect one of the types of subjects as recited, for example, in claims 35 or 36.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species Election I, claims 29, 30, 43, or 44.
Species Election II, claims 35, 36, 49, or 50.

The following claim(s) are generic:
Species Election I: claims 22-28, 31-36, 38-42, 45-50 and 52-55;
Species Election II: claims 22-34, 38-48, and 52-55.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species are mutually exclusive, i.e. a canine adenovirus could not be considered a non-canine adenovirus, and vice versa.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633